# PFIZER-BIONTECH COVID-19 VACCINE- rna ingredient bnt-162b2 injection, suspension Pfizer Manufacturing Belgium NV

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## Pfizer-BioNTech COVID-19 Vaccine

## PRINCIPAL DISPLAY PANEL - 1.8 mL Vial Label

PAA156051 LOT/EXP

Pfizer-BioNTech COVID-19 Vaccine After dilution, vial contains 5 doses of 0.3 mL

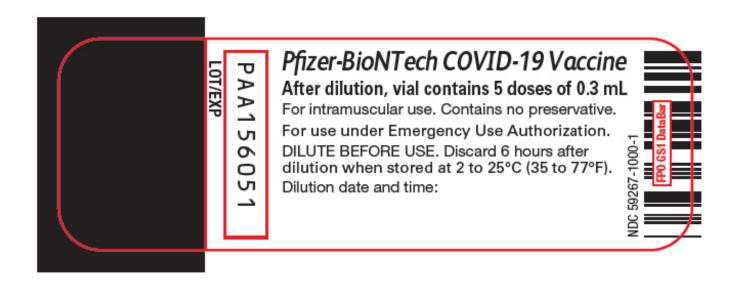
For intramuscular use. Contains no preservative.

For use under Emergency Use Authorization.

DILUTE BEFORE USE. Discard 6 hours after dilution when stored at 2 to 25°C (35 to 77°F).

Dilution date and time:

NDC 59267-1000-1



## PRINCIPAL DISPLAY PANEL - 195 Vial Carton

NDC 59267-1000-2

Pfizer-BioNTech COVID-19 Vaccine Suspension for Intramuscular Injection

195 Multiple Dose Vials (after dilution each vial contains 5 doses of 0.3 mL)

Pfizer | BIONTECH

STORAGE: Prior to dilution, store at -80°C to -60°C (-112°F to -76°F). Store in this carton to protect from light.

DOSAGE AND ADMINISTRATION: After

dilution, each vial contains 5 doses of 0.3 mL. See FDA-authorized Fact Sheet or scan QR code for information.

MUST BE DILUTED BEFORE USE with sterile 0.9% Sodium Chloride Injection, USP (not supplied). After dilution, store the vaccine at 2°C to 25°C (35°F to 77°F). Discard after 6 hours. Contains no preservative. For use under Emergency Use Authorization.

Rx only

Manufactured by Pfizer Inc New York, NY 10017

Manufactured for BioNTech Manufacturing GmbH An der Goldgrube 12 55131 Mainz, Germany

PAA156052

LOT: EXP:

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NDC 59267-1000-2

# Pfizer-BioNTech COVID-19 Vaccine

Suspension for Intramuscular Injection

195 Multiple Dose Vials

(after dilution each vial contains 5 doses of 0.3 mL)





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After dilution, store the vaccine at 2°C to 25°C (35°F to 77°F).

Discard after 6 hours. Contains no preservative.

For use under Emergency Use Authorization.

Rx only

LOT:

EXP:

Manufactured by Pfizer Inc New York, NY 10017 Manufactured for BioNTech Manufacturing GmbH An der Goldgrube 12

55131 Mainz, Germany

PAA156052

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## Pfizer-BioNTech COVID-19 Vaccine

Suspension for Intramuscular Injection 195 Multiple Dose Vials

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PAA156052

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## PFIZER-BIONTECH COVID-19 VACCINE

rna ingredient bnt-162b2 injection, suspension

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NDC:59267-1000 Product Type VACCINE Item Code (Source)

Route of Administration INTRAMUSCULAR

## Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength					
RNA ingredient BNT-162B2 (UNII: 5085ZFP6S) (RNA ingredient BNT-162B2 - UNII:5085ZFP6S)	RNA ingredient BNT- 162B2	0.23 g in 1.8 mL					

Inactive Ingredients					
Ingredient Name	Strength				
lipid ALC-0159 (UNII: PJH39 UMU6 H)					
lipid ALC-0315 (UNII: AVX8DX713V)					
POTASSIUM CHLORIDE (UNII: 660 YQ 98 I10)					
MONOBASIC POTASSIUM PHO SPHATE (UNII: 4J9 FJ0 HL51)					
SODIUM CHLORIDE (UNII: 451W47IQ8X)					
SO DIUM PHO SPHATE, DIBASIC, UNSPECIFIED FORM (UNII: GR686LBA74)					
<b>SUCROSE</b> (UNII: C151H8 M554)					

P	Packaging							
#	Item Code	Package Description	Marketing Start Date	Marketing End Date				
1	NDC:59267-1000- 2	195 in 1 CARTON						
1	NDC:59267-1000- 1	1.8 mL in 1 VIAL, GLASS; Type 0: Not a Combination Product						
2	NDC:59267-1000-3	25 in 1 CARTON						
2	NDC:59267-1000- 1	1.8 mL in 1 VIAL, GLASS; Type 0: Not a Combination Product						

Marketing Information						
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date			
UNAPPROVED DRUG OTHER		11/04/2020				

# **Labeler -** Pfizer Manufacturing Belgium NV (370156507)

# Registrant - Pfizer Inc (113480771)

Establishment						
Name	Address	ID/FEI	Business Operations			
Pfizer Manufacturing Belgium NV		370156507	PACK(59267-1000), MANUFACTURE(59267-1000), ANALYSIS(59267-1000), LABEL(59267-1000)			

Establishment							
Name	Address	ID/FEI	Business Operations				
Pharmacia and Upjohn Company LLC		618054084	MANUFACTURE(59267-1000), LABEL(59267-1000), PACK(59267-1000), ANALYSIS(59267-1000)				

Establishment						
Name	Address	ID/FEI	Business Operations			
Wyeth BioPharma Division of Wyeth Pharmaceuticals LLC		174350868	ANALYSIS(59267-1000), API MANUFACTURE(59267-1000)			

Establishment							
Name	Address	ID/FEI	Business Operations				
Pfizer Inc		004954111	ANALYSIS(59267-1000)				

Revised: 11/2020

Pfizer Manufacturing Belgium NV